NMS LABS

NMS Labs
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Phone: (215) 657-4900 Fax: (215) 657-2972
e-mail: nms@nmslabs.com
Robert A. Middleberg, PhD, DABFT, DABCC, Laboratory Director

CONFIDENTIAL

September 22, 2009

RECEIVED
SEP 25 2009
ERNST & MATTISON

TO: M60112
Ernst & Mattison
Attn: Terry Kilpatrick
1020 Palm Street
San Luis Obispo, CA 93401

SUPPLEMENTAL CRIMINALISTICS REPORT OF: McCORNACK SR., DANIEL ELWIN
NMS Workorder No: 09154008
Client ID No: Prior NMS Workorder No: 09107925

SPECIMENS: Item 1 Five white pills in a Cinnamon Altoids® container.

The above evidence was received from United State Postal Service Priority Mail on 07/13/09.

EXAMINATION: Analysis Requested – Test No. 7011 – Special Request for Digoxin

FINDINGS:

Item 1.a

DIGOXIN (by LC-MS/MS)	0.247 mg/pill
WEIGHT	122.939 mg
THICKNESS	3.28 mm

Item 1.b

DIGOXIN (by LC-MS/MS)	0.244 mg/pill
WEIGHT	127.597 mg
THICKNESS	3.56 mm

Item 1.c

DIGOXIN (by LC-MS/MS)	0.227 mg/pill
WEIGHT	129.432 mg
THICKNESS	3.59 mm

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NMS Workorder No: 09154008
Client ID No: Prior NMS Workorder No: 09107925

Item 1.d

DIGOXIN (by LC-MS/MS)	0.227 mg/pill
WEIGHT	128.525 mg
THICKNESS	3.54 mm

Item 1.e

DIGOXIN (by LC-MS/MS)	0.261 mg/pill
WEIGHT	127.690 mg
THICKNESS	3.52 mm

Respectfully,

Matthew McMullin, MS, DABFT
Forensic Toxicologist

MMM/sdw

This analysis was performed under chain of custody. The chain of custody documentation is on file at NMS Labs.

The remainder of the submitted specimens are scheduled to be returned/discarded six (6) weeks from the date of this report unless alternate arrangements are made by you prior thereto.

***** ***** ANALYSIS SUMMARY ***** *****

Test No. 7011 – Special Request – Liquid Chromatography – Tandem Mass Spectrometry on Pill for: Digoxin.

***** END OF REPORT *****

CVS Caremark
Recall Letter

CVS CAREMARK | CAREMARK®

May 2008

Dear Plan Participant:

You recently received a letter from CVS Caremark about the Digitek® (digoxin tablets, USP) 0.125 mg and Digitek (digoxin tablets, USP) 0.25 mg Patient Level Recall. We are providing you with an important update.

Please be aware that as a result of this recall, there is a market-wide shortage of digoxin. In an effort to meet the needs of all plan participants, enclosed is a maximum of a 45-day supply of replacement product.

What to Do with Your Digitek
For your safety and to ensure proper disposal, we have provided you with a return envelope. Please send your Digitek tablets to CVS Caremark in the original prescription bottle, if possible.

We encourage you to contact your provider with any questions or concerns regarding continuation of therapy.

Sincerely,

CVS Caremark

Enclosure

For more information on this issue you may contact the U.S. Food and Drug Administration (FDA) consumer inquiry line toll-free at 1-888-INFO-FDA (1-888-463-6332) or by accessing the FDA Web site at www.fda.gov.

FDA Statement

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek® (digoxin tablets, USP) as precaution

Contact:
Stericycle customer service
1-888-276-6166

FOR IMMEDIATE RELEASE -- Morristown, NJ -- April 25, 2008 -- Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class I nationwide recall of Digitek® (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than it appropriate.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received.

Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

Any customer inquiries related to this action should be addressed to Stericycle customer service at 1-888-276-6166 with representatives available Monday through Friday, 8 am to 5 pm EST. Additional information about the voluntary recall can also be found at www.actavis.us.

Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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Drugs

Facts and Myths about Generic Drugs

Today, 7 in 10 prescriptions filled in the United States are for generic drugs. This fact sheet explains how generic drugs are made and approved and debunks some common myths about these products.

FACT: FDA requires generic drugs to have the same quality and performance as the brand name drugs.

- When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass produced, very small variations in purity, size, strength and other parameters are permitted. FDA puts limits on how much variability in composition or performance of a drug is acceptable.
- Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name (or reference) product. Generic drugs do not need to contain the same inactive ingredients as the brand product.
- Through review of bioequivalence data, FDA assures that the generic product will perform the same as its respective brand name (or reference) product. This standard applies to all generic drugs, whether immediate or controlled release.
- A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same. In that case, there is no need to carry out a clinical effectiveness study and they are not required.
- All generic manufacturing, packaging and testing sites must pass the same quality standards as those of brand name drugs and the generic products must meet the same exacting specifications as any innovator brand name product. In fact, many generic drugs are made in the same plants as innovator brand name drug products.
- If an innovator of a brand name drug switches drug production to an alternative manufacturing site, or they change formulation of their brand name drug, these companies are held to the same rigorous manufacturing requirements as those that apply to generic drug companies.

FACT: Research shows that generics work just as well as brand name drugs.

- A recent study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs. [Kesselheim et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526].

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85% lower than the brand name product.

- An IMS National Prescription Audit shows that a typical formulary now charges $6 for generic medications, $29 for preferred branded drugs, and $40 or more for non-preferred branded drugs. [Aitken et al. Prescription drug spending trends in the United States: looking beyond the turning point. Health Aff (Millwood). 2009;28(1):w151-60].
- Independent research has shown that total prescription drug expenditures in the United

Dec 17 2009 9:21 P.02

FORENSIC MEDICAL
REQUEST FOR PROFESSIONAL BILLING

Bill To: Tucker Ellis & West
ATTN: Matthew Moriarity
Address: 1150 Huntington Bldg
925 Euclid Avenue
City/State/Zip: Cleveland Ohio 44115-1414
Phone # 216-592-5000

Date or Period Billed: McCornack

Regarding Case: ✓

Work Done (Consultation, Deposition, Testimony, etc.)

Fee Calculation:

Total Hours: 2.5

Rate Per Hour: X

Total Professional Fee: $ 500

Less Retainer Paid: $ -0-

Balance of Professional Fee Due = $ 1250

Other Fees: (for example, copies, parking, taxi, food, etc.)

Description: _____ $ _____

Description: _____ $ _____

Description: _____ $ _____

TOTAL BILLABLE $ 1250.00

Requested By: [signature]

Date: 12-17-09

Forward form to Accounting for processing of invoice.

10:21:99

(Charge Policy on Reverse)

Res Commun Chem Pathol Pharmacol. 1986 Apr;52(1):141-4.

Digoxin concentrations in postmortem human tissues.

McKercher HG, Mikhael NZ, De Gouffe M, Lukaszewski T, Peel HW.

An extraction procedure is described that allows the application of a commercially available enzyme-multiplied immunoassay technique to the measurement of digoxin in whole blood, liver, and kidney. The concentrations of digoxin were measured in tissues obtained at autopsy from five patients who had been taking therapeutic doses of digoxin prior to death. Blood concentrations at autopsy were found to be higher than the therapeutic range, perhaps due to postmortem redistribution. Liver concentrations of digoxin showed a positive correlation with blood concentrations; this was not found for kidney concentrations of the drug.

PMID: 3520728 [PubMed - indexed for MEDLINE]